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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,389	10/21/2003	Benjamin Oshlack	6750-362-999	2376

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EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
06/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,389	OSHLACK ET AL.	
	Examiner	Art Unit	
	FRANK I. CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *70-97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20070620*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/20/2007 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 70-97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicant submits new claims which indicate AUC range, Cmax range and Tmax range and in a number of claims this is combined with a percentage range comparison of said values to an immediate release formulation of the same dosage. The Applicant cites to various paragraphs and Tables of the Specification as support for the claims. However, the same do not provide support for subject matter indicated above in that there is no disclosure which recites a range for AUC, Cmax and Tmax or percent comparison to an immediate release formulation of the same dosage. Further, the only immediate release formulation tested was Dilaudid ®, an 8 mg tablet containing specific excipients, which was compared against capsules containing pellets

in which the total dose was 8 mgs of hydromorphone with specific excipients. There is no basis for concluding that all immediate release formulations would have the same AUC, Cmax and Tmax as Dilaudid ®. See e.g. US Pat. 5,622,722, Table 1 (different normal release formulations exhibited different in vitro dissolution characteristics). Also, AUC, Cmax and Tmax are also affected by the characteristics of the individual taking the formulation at the time the test was done and the excipients and dosage form used. See PDR, values for AUC, Cmax and Tmax of Dilaudid ® are different from the values obtained by the Applicants and even between the different tests disclosed in the Specification. As such, the disclosure cannot provide support for the subject matter claimed above. See *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) ("If n- propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it."); *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) ("the specification does not clearly disclose to the skilled artisan that the inventors ... considered the ratio... to be part of their invention .... There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion").

Claims 70-97 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific formulations prepared which resulted in the specific AUC,

Cmax and Tmax observed, the specification does not reasonably provide enablement for any extruded blend divided into a unit dosage form containing the claimed hydrophobic materials and hydrophobic fusible carriers and 8 mg of hydromorphone or salt thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The nature of the invention:

The invention is directed to sustained release oral dosage forms containing hydromorphone and the claimed hydrophobic materials and hydrophobic fusible carriers in an extruded blend which is divided into unit dosage forms in wherein the oral dosage form when containing 8 mg has the claimed ranges of AUC, Cmax and Tmax and in some claims a percentage range of the same compared to an immediate release formulation.

The state of the prior art and the predictability or lack thereof in the art:

The prior art discloses sustained release oral dosage forms of hydromorphone, however, there is no indication as what other formulation would result said AUC, Cmax or Tmax. As such, predictability in the art appears to be low.

The amount of direction or guidance present and the presence or absence of working examples: Other the specific formulations, i.e. capsules containing pellets containing the specified excipients, that resulted in as specific AUC, Cmax or Tmax, and the 8 mg Dilaudid ® tablet, the specification lists numerous possible excipients which could be used to prepare a dosage form. However, there is no indication as to what other formulations would result in the the specific AUC, Cmax or Tmax or other immediate release dosage forms.

The breadth of the claims and the quantity of experimentation needed:

The claims are broad in that there are numerous possible combinations of the claimed excipients and oral dosage forms and in some of the claims any immediate release oral dosage formulation containing 8 mg of hydromorphone or a salt thereof. As such, one of ordinary skill in the art would be required to do undue experimentation in order to determine what other formulations containing 8 mg of hydromorphone or a salt thereof would result in an AUC, Cmax and Tmax falling within the scope of the claims.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Applicant has not provided any evidence that any combination of the hydrophobic materials, hydrophobic fusible carriers, oral dosage forms containing 8 mg of hydromorphone or salt thereof and where indicated in comparison with any immediate release oral dosage form would result in the claimed AUC, Cmax and Tmax ranges. As such, one of ordinary skill in the art would still be required to do undue experimentation in order to determine what other formulations would result in the same.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 70-75, 77-88, 90-97 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-5,8-21,24-66 of U.S. Patent No. 5,965,161. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both disclose extruded multiparticulate compositions, which can be compressed into tablets or placed in gelatin capsules, containing hydromorphone, hydrophobic materials, hydrophobic fusible carriers having the claimed melting point, and can contain stearic acid, be in powder form prior to extrusion and contain plasticizers.

Claims 70-72, 75, 77-81, 86-88, 90-92, 97 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5,8-21, 24-37 of U.S. Patent No. 6,335,033 or claims 1-8, 10-25,27 of U.S. Patent No. 6,261,599. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both disclose extruded multiparticulate compositions, which can be compressed into tablets or placed in gelatin capsules, containing hydromorphone, hydrophobic materials, hydrophobic fusible carriers having the claimed melting point.

Claims 70-72, 75, 77-78, 80,81, 86-88, 90, 92, 97 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 7-17, 19, 22, 2438 of U.S. Patent No. 6,706,281. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both disclose extruded multiparticulate

compositions, which can be placed in gelatin capsules, containing hydromorphone, hydrophobic materials, hydrophobic fusible carriers having the claimed melting point.

Claims 70-81, 86-92, 97 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 10-16, 18-32, 41-50,62 of U.S. Patent No. 5,958,452. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both disclose extruded multiparticulate compositions, which can be compressed into tablets or placed in gelatin capsules, containing hydromorphone, hydrophobic materials, hydrophobic fusible carriers having the claimed melting point, where the components can be in powder form prior to extrusion and extruding can be performed under vacuum conditions to provide a substantially non-porous extrudate.

Claims 70-72, 75, 77-88, 90-97 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 10-24, 27-29, 32 of U.S. Patent No. 6,743,442. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both disclose extruded multiparticulate compositions, which can be compressed into tablets or placed in gelatin capsules, containing hydromorphone, hydrophobic materials, hydrophobic fusible carriers having the claimed melting point, and can contain lubricants and plasticizers.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
June 2, 2008

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616